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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-------------------------|------------------------------|------------------|
| 10/644,639 | 08/20/2003 | Xiao-Zhuo Michelle Wang | A32815-I -I - 072667.0190 | 7944 |
| 7590 | 09/19/2005 | | EXAMINER | |
| BAKER BOTTS L.L.P. 44 TH FLOOR 30 ROCKEFELLER PLAZA NEW YORK, NY 10112-0228 | | | ULM, JOHN D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1649 | |

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Q W

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/644,639 | WANG ET AL. |
| | Examiner | Art Unit |
| | John D. Ulm | 1649 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 30-37 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 23-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 August 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

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1) Claims 1 to 37 are pending in the instant application.

2) Claims 1 to 22 and 30 to 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 July of 2005.

3) The information disclosure statement filed 20 August of 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

4) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code.in line 10 on page 5 and line 11 on page 25. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(p), which states that:

"When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. If hyperlinks and/or other forms of

browser-executable code are embedded in the text of the patent application, examiners should object to the specification and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion."

Correction is required.

5) The figure in the instant application does not comply with 37 C.F.R. § 1.84(U)(1), which states that " [where only a single view is used in an application to illustrate the claimed invention, it must not be numbered and the abbreviation "FIG" must not appear".

6) The sequences presented on pages 18 to 20 and 22 to 24 are objected to because the specification (including the abstract and claims), and any amendments for applications, except as provided for in 37 CFR 1.821 through 1.825, must have text written plainly and legibly either by a typewriter or machine printer in a nonscript type font (e.g., Arial, Times Roman, or Courier, preferably a font size of 12) lettering style having capital letters which should be at least 0.3175 cm. (0.125 inch) high, but may be no smaller than 0.21 cm. (0.08 inch) high (e.g., a font size of 6) in portrait orientation and presented in a form having sufficient clarity and contrast between the paper and the writing thereon to permit the direct reproduction of readily legible copies in any number by use of photographic, electrostatic, photo-offset, and microfilming processes and electronic capture by use of digital imaging and optical character recognition; and only a single column of text. See 37 CFR 1.52(a) and (b). Correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7) Claims 23, 25, 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to an assay that measures the binding to, or modulation of, a glutamate-gated chloride channel. Whereas one could produce a purified glutamate chloride channel subunit of the instant invention and employ it in such an assay, that assay would be inoperative. A glutamate-gated chloride channel of the instant invention is a member of a protein family known as ligand-gated ion channels (a.k.a. ionotropic receptors). As illustrated by the section entitled "The Structure of Ligand-Gated Ion Channels" and Figure 2 of the Nakanishi publication (SCIENCE 258:597-603, 23 Oct. 1992), each and every member of this protein family functions as either a homo- or hetero- pentameric transmembrane structure that forms an ion channel within a biological membrane. The amino acid sequence presented in SEQ ID NO;14 of the instant application does not correspond to a glutamate-gated chloride channel. That sequence is the amino acid sequence of a subunit of a glutamate-gated chloride channel that is capable of functioning as a homo-pentameric structure composed of five identical subunits. Each of those subunits contains two extracellular termini, three loops and four transmembrane domains. Therefore, a complete channel has ten extracellular termini, fifteen loops and twenty transmembrane domains. Because of the complex structure of a glutamate-gated

chloride channel of the instant invention, one of ordinary skill in the art has no expectation that such a channel will function outside of the context of a cell membrane.

8) Claims 23, 24, 26, 27, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As shown by Figure 1 of the Nakanishi publication, the employment of glutamate-gated ion channels in the identification of agonists and antagonists thereto was a practice that was old and well known in the art at the time of the instant invention. Therefore, the novelty of the claimed invention is found in the lepidopteran glutamate-gated chloride channel employed therein. Whereas the claims encompass a method that could employ any one of potentially thousands or tens of thousands of protein complexes encompassed by the limitation "lepidopteran glutamate-gated chloride channel", the instant specification does not provide an adequate written description of the potentially very large genus of proteins encompassed by this limitation. *In re Clarke*, 148 USPQ 665, (CCPA 1966) held that;

" It appears to be well settled that a single species can rarely, if ever, afford support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlfors* et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising

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hundreds of species, a considerably large number of reductions to practice would probably be necessary."

In the instant case, the specification only describes a single species of the claimed genus. In the decision of *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997), the court held that:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of a of single isolated DNA encoding particular lepidopteran glutamate-gated chloride channel subunit having very specific physical and structural properties, the instant specification does not provide a structural formula which is definitive of all lepidopteran glutamate-gated chloride channel subunits. Whereas the instant specification and prior art may identify some properties which are common to all ligand-gated ion channels, it does not identify

those defining structural elements which provide the functional and structural properties that distinguish a lepidopteran glutamate-gated chloride channel subunit from other glutamate gated ion channel subunits.

9) Claims 23 to 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,780,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented subject matter is fully encompassed by the pending claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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